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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,665	11/17/2003	Mark Selby	PP01635.007	5235

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/715,665	SELBY ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-37,42-45,66-69,77 and 80-91* is/are pending in the application.

4a) Of the above claim(s) *80-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-37,42-44,66-68,77 and 85-87* is/are rejected.

7)☒ Claim(s) *45, 69, and 88-91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 34-37, 42-45, 66-69, 77, 80-91 are pending in the application.

2. In the prior action, mailed on August 14, 2006, claims 34-37, 42-45, 66-69, 77, and 80-88 were pending; with claims 80-84 withdrawn as to non-elected inventions; and claims 34-37, 42-45, 66-69, 77, and 85-88 rejected.

3. In the Response of December 14, 2006, the Applicant amended claims 34, 37, 42, 45, 66, 69, 77, 85, and 88; cancelled claim and added new claims 89-91.

4. Currently, claims 34-37, 42-45, 66-69, 77, and 85-88 are pending and under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Withdrawn)** Claims 34, 35, 37, 42, 43, 45, 66, 67, 69, 77, and 85-88 were rejected under 35 U.S.C. 112, first paragraph, as lacking sufficient written description support for nucleotides encoding the genus of peptides comprising immunogenic sequences having at least about 90% identity to an HCV sequence. In view of the amendment of the claims such that they now require the presence of at least one native HCV epitope, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 34-36, 42-44, and 66-68 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Major et al. (J Virol 69: 5798-5805- of record in the Nov. 2003 IDS) in view of Michalak et al., (J Gen Virol 78: 2299-2306), and further in view of Valenzuela et al. (Bio/Technology 3: 323-26- also of record in the Nov. 2003 IDS). The Applicant traverses this rejection on the grounds that none of the cited references specifically teach or suggest the claimed nucleic acid encoding a HBsAg/E2 fusion protein; and that the Major reference teaches away from such a fusion protein. These arguments are not found persuasive. The argument that no one of the cited references teaches the specific nucleic acid claimed has been previously addressed. As was previously indicated, the present rejection is not based on any one reference, but on the combination.

With respect to the assertion that the Major reference teaches away from the claimed invention, the Examiner does not agree. The Major reference does question the utility of the E2 antigens as a vaccine antigen, however, other teachings in the art clearly indicate that the E2 antigen was (an is) still considered a viable anti-HCV vaccine antigen up to the time of the filing of the present application, despite knowledge in the art regarding the heterogeneity referred to by Major. See e.g., Michalak, page 2305 (the Michalak reference being published two years after Major). See also, Fournillier et al., J Virol 73: 7497 at (e.g.) 7502-03; and Esumi et al., Arch Virol 144: 973-80, at 979 (indicating that, although there is heterogeneity among the E2 proteins,

there also appears to be cross-reactivity among the sequences). Additional teachings in the art indicate that the problem may be addressed by combining the sequences of several E2 sequences. See e.g., Esumi et al., Virology 251: 158-64 at (e.g.) 162-63. Thus, while the teachings of Major raise concerns in the art, these concerns are addressed by other teachings in the art such that those of ordinary skill in the art would still have been motivated to make the claimed composition.

Furthermore, while the art indicates that the suitability of the E2 protein as a vaccine antigen may be unclear, the antibodies that may be produced against such proteins have other uses, such as in HCV diagnostics. See e.g., Cardoso et al., J Med Virol 55: 28-34 (suggesting on page 29 the use of anti-E2 antibodies in immunohistology assays). Thus, those in the art would have had sufficient motivation to make the nucleotides suggested by the identified references such that such anti-E2 antibodies could be produced even if the composition was not considered to be a potential anti-HCV vaccine.

The Applicant further asserts that there would have been no motivation to alter the E2 protein component of any E2 fusion encoded by a nucleic acid as suggested by Michalak because that reference was concerned with the protein, and not a nucleic acid. This argument is not found persuasive because the Michalak reference indicates that this protein can be efficient secreted, and is immunologically a functional equivalent for the full-length protein. Those in the art would therefore have been motivated to use such a modified E2 in a nucleic acid encoding an HBsAg/E2 fusion so as to ensure the secretion of the fusion protein, and for the reasons previously described.

Applicant's additional arguments of pages 15 and 16 are noted. The Applicant appears to be indicating that a specific suggestion to combine the references be found in the prior art cited. Such is not a requirement under 35 U.S.C. 103. Because both reasons for the combination of the teachings of the references, and grounds by which those of ordinary skill in the art would have had a reasonable expectation of success were provided (i.e., the rejection is not based merely on the identification of the elements in the prior art), and as these do not rely on the teachings of the present application, this additional argument by the Applicant is also not found persuasive.

For these reasons, and for the reasons of record, Applicant's arguments in traversal are not found persuasive, and the rejection is maintained.

9. **(Prior Rejection- Maintained)** Claims 77 and 79 were rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (U.S. 6,306,625), in view of Major, Michalak, and Valenzuela as applied to claims 34-36, 42-44, and 66-68 above. The Applicant traverses this rejection on the basis that Jacobs does not teach or suggest the fusion of HBsAg with an HCV antigen. This argument is not found persuasive in view of the inclusion of the Major and Michalak references in the statement of the rejection, and for the reasons indicated above with respect to claims 34-36, 42-44, and 66-68.

10. **(Prior Rejection- Maintained)** Claim 37 was rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela as applied to claim 77 above, and further in view of the teachings of and GenBank Accession Numbers X02763, and

M62321. The Applicant traverses the rejection based on the assertion that the cited art provides no motivation to combine an HBsAg sequence with an HCV E2 sequence. In view of the inclusion of the teachings of the Major and Michalak references as described previously and above, and for the same reasons as indicated with respect to the teachings of Major and Michalak in the rejection of claims 34-36, 42-44, and 66-68 above, this assertion is not found persuasive. The rejection is therefore maintained.

11. **(Prior Rejection- Maintained)** Claims 85-87 were rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela as applied to claims 77 above, and further in view of De Wilde et al. (U.S. 5,928,902), U.S. 4,722,840 (the 840 patent- of record in the November 2003 IDS), and Mountford et al (PNAS 91: 4303-07). The Applicant traverses this rejection for substantially the same reasons as described above, and as were asserted previously. These arguments are not found persuasive for the reasons above and in the prior actions. The rejection is therefore maintained.

12. **(Prior Rejection- Withdrawn)** Claim 88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela, further in view of De Wilde et al. (U.S. 5,928,902), U.S. 4,722,840 (the 840 patent- of record in the November 2003 IDS), and Mountford et al (PNAS 91: 4303-07) as applied to claims 85-87, further in view of the teachings of GenBank Accession Numbers X02763, and M62321 as applied to claim 37. It is agreed that the teachings in the art do not teach or suggest the specific vector of SEQ ID NO: 6. The rejection is therefore withdrawn.

Conclusion

13. No claims are allowed. Claims 45, 69, and 88-91 appear to be allowable over the prior art. The prior art does not appear to teach or suggest the vector of SEQ ID NO: 6, or the specific protein sequence of SEQ ID NO: 7. However, these claims are objected to for depending on rejected claims.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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